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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,973	09/18/2003	Quang Tran	006701.P035	5340

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EXAMINER
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DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,973	<b>Applicant(s)</b> TRAN ET AL.	
	<b>Examiner</b> Annette F. Dixon	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28-35,37-44 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-35,37-44 and 55-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is in response to the request for continued examination filed on March 29, 2010. Examiner acknowledges claims 28-35, 37-44, and 55-59 are pending in this application, with claims 28, 31, 39, and 56 having been currently amended, claim 59 having been newly added, and claims 1-27, 36, and 45-54 having been cancelled.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2010 has been entered.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 28-35, 37-44, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198).

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As to Claim 28, Saadat disclose a system for delivering a contraceptive device (50) within a fallopian tube (Figure 2), the system comprising: a catheter (100) comprising a lumen (110), a distal portion (101) and a proximal portion (107), a contraceptive device (50) releasably disposed at least partially within the lumen (110) of the catheter (100) near the distal portion (101); and a deployment member (120) in detachable engagement with the contraception device (50) for deploying the contraceptive device (50) from the catheter (100) (Figure 11, Figure 13, and Column 10, Lines 30-31). Yet, Saadat does not teach the particulars of the catheter having a coil disposed along the catheter body and extending along the distal and proximal portions, nor the varying degrees of flexibility. Berhow teaches a medical catheter (10) having a coil (16) which extends along the length of the catheter from the distal end (13) to the proximal end (12) where along the catheter (10) the flexibility of the changes for the purpose of having a reinforced catheter with resistance to kinking that may result in trauma to the patient (Figures 1-4A, Paragraphs 0061 and 0071). Further, Berhow discloses outer layer (17) of the lumen (15) constrains the coil (16) and is made of varying durometers (hardness) along its length representative of changes in flexibility. (Paragraphs 0062 and 0063). Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter of Saadat to include a coil having varying degrees of flexibility along the length of the catheter as taught by Berhow to provide a reinforced catheter having additional safety features to prevent patient trauma as a result of kinking.

As to Claims 29, 37, 38, 56 Berhow teaches the medical catheter is most flexible (or least hard) at the distal end and increasingly becomes less flexible (or more hard) towards the proximal end (12). (Paragraph 0061).

As to Claim 30, Berhow teaches the catheter (10) is made from multiple layers in the distal portion (13) and having a coil (16) in one of the layers. (Figures 1-3 and Paragraphs 0038 and 0051).

As to Claims 31-35 and 39-42, Berhow teaches the multiple layers comprise: an inner layer (14, polytetrafluoroethylene), a middle layer (16, stainless steel coil) and an outer layer (17, polyurethane). (Figures 1-3 and Paragraphs 0019, 0021, 0024, 0038, and 0051).

As to Claims 43, 44, and 58, Berhow teaches the use of a radiopaque marker (19) or tracer ring on the catheter (10) to permit visualization of the catheter within the patient. (Paragraphs 0058 and 0059).

As to Claim 57, Berhow teaches a tapered region (32) and a lumen (15) that extends throughout the catheter (10). (Paragraph 0038).

5. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Shepherd (3,566,874).

As to Claim 55, the modified Saadat teaches a reinforced medical catheter for delivering a contraceptive device, yet does not expressly disclose the use of a hydrophilic coating over the distal portion of the catheter. Shepherd teaches the use a

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hydrophilic coating over the distal end of the catheter for the purpose of reducing the irritation and infection associated with the normal use of catheters. (Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter of the modified Saadat to include a hydrophilic coating over the catheter as taught by Shepherd for the purpose of preventing infection.

6. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Peters (5,441,485).

As to Claim 59, the modified Saadat teaches a reinforced medical catheter for delivering a contraceptive device having flexibility as a result of differing durometers (hardness) along the length of the catheter. Yet, the modified Saadat does not expressly disclose the varying of the thickness of the catheter along its length for imparting flexibility. Peters teaches the manner of imparting flexibility to a catheter can be achieved by multitude of alternative manufacturing processes including but not limited to: varying the thickness, molding sections out of different materials each having different durometers, or a combination thereof. (Column 3, Line 28 thru Column 4, Line 1). Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter manufacturing method for imparting flexibility of the modified Saadat, to include the alternative catheter manufacturing method of varying the thickness of the catheter, as taught by Peters as an alternative method by which the catheter can have varying degrees of flexibility along its length.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims, filed March 29, 2010, have been considered but are moot in view of the new ground(s) of rejection.

Regarding the combination of the Saadat in view of Berhow, Applicant asserts the newly recited imitations of "an outer layer of varying thickness or durometer rating along the length of the coil extending along the distal end" are not disclosed. However, Berhow discloses the catheter (40) having a coiled member (46), and outer layer (17) of the lumen (15) constraining coiled member (46). Additionally, Berhow teaches the catheter (40) is made of varying durometers (hardness) along its length representative of changes in flexibility. (Paragraphs 0062 and 0063). Consequently, the softer durometer rating at 40A is more flexible than the harder durometer rating at 40B, therein enabling additional safety features to prevent patient trauma as a result of kinking (Paragraph 0071). In light of the aforementioned reasoning, the rejection of the claims has been maintained despite the newly recited claim limitations.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon  
Examiner  
Art Unit 3771

/Annette F Dixon/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771